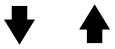
Operations/Service Manual

smith&nephew

VULCAN® Generator

CE 0086

Glossary of Symbols

NON-STERILE	Non-Sterile
	Dangerous Voltage: Danger of electric shock
	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.
	Fragile; handle with care
	This Way Up
	Keep Dry
	Neutral (Return) Electrode Connector (Split Grounding Pad)
	Defibrillator Proof Type BF Equipment
	Equipotentiality
	Alternating Current
	Non-ionizing Electromagnetic Radiation
	Protective Earth (ground)
	Footswitch
	EU: Not for general waste
	UL Classification
	Fuse
	Amplitude Control
	ON
	OFF
	Up and Down Buttons
	Temperature Range
	Humidity
EC REP	European Representative
	Service lifetime in years

Preface

This manual provides the information required to operate and maintain the Smith & Nephew VULCAN® Generator. It is essential that all the information in this manual and on the generator label is read and understood before using or maintaining the equipment.

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Introduction

The Smith & Nephew VULCAN• Generator is designed to provide finely-controlled radiofrequency (RF) energy for the coagulation, cutting, ablation, and hemostasis of soft tissue during a variety of surgical procedures. The generator control unit is specifically designed for use with Smith & Nephew temperature-controlled and power-controlled probes.

Device Description

The generator control unit is a line-voltage powered, radiofrequency generator capable of delivering up to 200 watts of power. The generator control unit includes a neutral electrode monitor (NEM) to monitor split grounding pad contact quality. It is designed to be used only with Smith & Nephew temperature-controlled, cutting, and ablation probes and includes the following features:

- Two RF output modes: **Temperature Control Mode**, where the output power is software-controlled to maintain a specified tissue temperature; and **Power Control Mode**, used for cutting, ablation, and hemostasis.
- Numerical displays for impedance, set power, delivered power, set temperature, actual temperature, set cut, set coagulation, and preset selections.
- Message display for text messages.
- Indicators for electrode type (monopolar or bipolar), mode (Temperature Control or Power Control), stand-by, RF power on, RF output type (cut or coagulation), fault, and split grounding pad monitoring. NEM monitors the split grounding pad connection during surgery, discontinuing RF delivery if a fault in the NEM monitor circuit is detected.
- A probe recognition system: the generator control unit automatically selects the appropriate mode and preset settings for the probe type.

The Smith & Nephew VULCAN Generator software can be upgraded at the customer's location with a Smith & Nephew supplied PCMCIA card. For information regarding software upgrades, please contact your authorized Smith & Nephew representative.

Indications for Use

The Smith & Nephew VULCAN Generator is indicated for general surgical purposes, including orthopedic and arthroscopic applications, for coagulation, ablation, and hemostasis of soft tissues in combination with Smith & Nephew temperature-controlled, cutting, and ablation probes.

Contraindications

There are no known absolute contraindications to the use of electrosurgery.

The use of the Smith & Nephew VULCAN Generator and accessories is contraindicated, when, in the judgment of the physician, an electrosurgical procedure would be contrary to the best interest of the patient.

⚠ Warnings

- **It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.**
- **Read these instructions completely prior to use.**
- **DANGER: Risk of explosion if used in the presence of flammable anesthetics, skin preparation agents, or biointestinal gases.**
- **Hazardous electrical output. This equipment should be used only by qualified medical personnel trained in the use of electrosurgery devices.**
- **This device has been tested and verified to comply with the IEC 60601-2-2. This exceeds the requirements specified by FCC part 18 for ISM equipment. This device is intended for operation in a medical facility only. Usage in a residential environment will likely cause unacceptable RF interference for which the user is held responsible.**
- **The generator control unit must be powered from a properly grounded 120–240 VAC, single-phase supply. Excessive risk (leakage current) may result if this equipment is connected to other than the manufacturer's recommended power distribution system.**
- **Risk of burns or fire. Do not use near conductive materials such as metal bed parts, inner-spring mattresses, etc.**

- Check that the electrical equipment is properly grounded (i.e. plugs contain a ground prong). The generator control unit must be plugged into a hospital-grade AC outlet.
- Safe use of monopolar electrosurgery demands proper grounding of the patient and proper insulation between the patient and any metal surfaces. A split pad with a surface area of at least 20 square inches (130 cm^2) is required. Valleylab™ REM™ pads (REF 7209687) meet this dimensional requirement and are recommended by Smith & Nephew for use with the VULCAN° Generator. Pads with a surface area of less than 20 square inches may have a lower dispersive effect. It is the responsibility of the user to qualify any alternate ground pad.
- Use of an inadequate ground pad or incorrect placement of the ground pad may result in a burn injury to the patient.
- Improper probe usage may result in patient burns at the return pad. To avoid this, follow the manufacturer's Instructions for Use.
- Do not exceed the RF duty cycle for the probe.
- Do not withdraw the probe while energy delivery is activated; this may result in an unintended patient burn or ignition of flammable materials.
- When using RF surgical equipment, keep the working part of the RF probe's active electrode in the field of view to avoid accidental RF burns. Avoid contact of the probe with metal parts of the scope and other conductive accessories by ensuring, before activation of the RF probe, that the active electrode is at sufficient distance from the tip of the scope.
- Failure of the radiofrequency surgical equipment could result in unintended increase of output power.
- Burns to the surgeon's hands may be possible if a probe comes into contact with a metal instrument or surface.
- Use of electrosurgery in patients with internal or external pacemakers, implantable defibrillators or monitoring equipment may require special considerations. The attending cardiologist and/or the pacemaker manufacturer should be consulted prior to surgery.
- The operating table should be grounded.
- During monopolar electrosurgery the patient should not come into contact with any metal parts which are grounded or which have appreciable capacitance to earth (operating tables, supports, etc.). The use of anti-static sheeting is recommended for this purpose.
- During monopolar electrosurgery skin-to-skin contact (i.e., between the arms and body of the patient) should be avoided. Insertion of dry gauze or its equivalent is recommended.
- The probe cables and extension cable should be positioned in such a way that contact with the patient or other leads is avoided. Probes not in use should be stored isolated from the patient.
- Incorrect actual temperature readings may result in improper treatment. Verify that the TEMPERATURE display reads the expected value (room temperature or body temperature) prior to treatment. If the TEMPERATURE reading is not accurate, check the device and connectors for damage, moisture, or contamination. Clean or replace as needed.
- If desired tissue effect is not being achieved, do not increase power beyond the normal range without first inspecting the integrity of the probe and neutral (return) electrode.
- To prevent electric shock, unplug the control unit from the electrical outlet before attempting to replace the fuses.
- To avoid fire hazard, use only fuses of the correct type, voltage rating, and current rating.
- To prevent electric shock, do not remove the control unit cover. There are no user-serviceable components inside. Dismantling the equipment will void the warranty. Refer servicing to qualified Smith & Nephew personnel.

Precautions

℞ ONLY U.S. Federal law restricts this device to sale by or on the order of a physician.

- Prior to each use, inspect the device to ensure it is functioning properly and not damaged. Do not use a damaged device.
- The Smith & Nephew VULCAN• Generator is designed specifically for use only with Smith & Nephew arthroscopic radiofrequency probes. Do not use other devices with the generator control unit.
- Check the probe and extension cable connections for the presence of liquid before use or whenever a probe is connected or disconnected during a procedure. Liquid may enter the connection during a procedure. ANY liquid can cause the connections to short, resulting in erroneous probe recognition or damage to the probe, cable, or generator control unit.
- Check the generator control unit's LCD message display to ensure that the proper probe identification and settings are displayed prior to beginning any procedure.
- Use the lowest RF power setting necessary to achieve the desired tissue effect.
- This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:
  - Reorient or relocate this equipment, the other equipment, or both.
  - Increase the separation between the pieces of equipment.
  - Connect the pieces of equipment into different outlets or circuits.
  - Consult a biomedical engineer.
- This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.
- Inspect all components, including extension cables and power cord, regularly for wear. Pay particular attention to extension cable insulation. Replace if evidence of deterioration is noted.
- Apparent low output or failure of the generator control unit to function properly at normal operating settings may indicate faulty application of the split grounding pad.
- When the generator control unit is used simultaneously with physiological monitoring equipment on the same patient, any monitoring electrodes should be placed as far from the surgical electrodes as possible. Needle monitoring electrodes are not recommended. Monitoring systems using high frequency current-limiting devices are recommended.
- Use only the power cord and connector specified for this unit.
- Electrical safety testing should be performed by a biomedical engineer or other qualified person.
- Do not immerse the footswitch cable.

Unpacking and General Inspection

Carefully unpack and inspect all of the components shipped with the Smith & Nephew VULCAN Generator. The following should have been received:

Quantity	Description
1	Smith & Nephew VULCAN Generator (REF 7210812)
1	Smith & Nephew VULCAN Footswitch (REF 7209692)
1	Hospital-grade power cord, country-specific
1	Smith & Nephew VULCAN Generator Operations/Service Manual (REF 1061526)

The Smith & Nephew VULCAN Extension Cable (REF 7209693) is available as an accessory for use with probes that do not include an integrated cable.

If any parts are missing or damaged, please contact your authorized Smith & Nephew sales representative. Save the carton and packing materials in the event that a component needs to be returned for repair.

Front Panel Layout

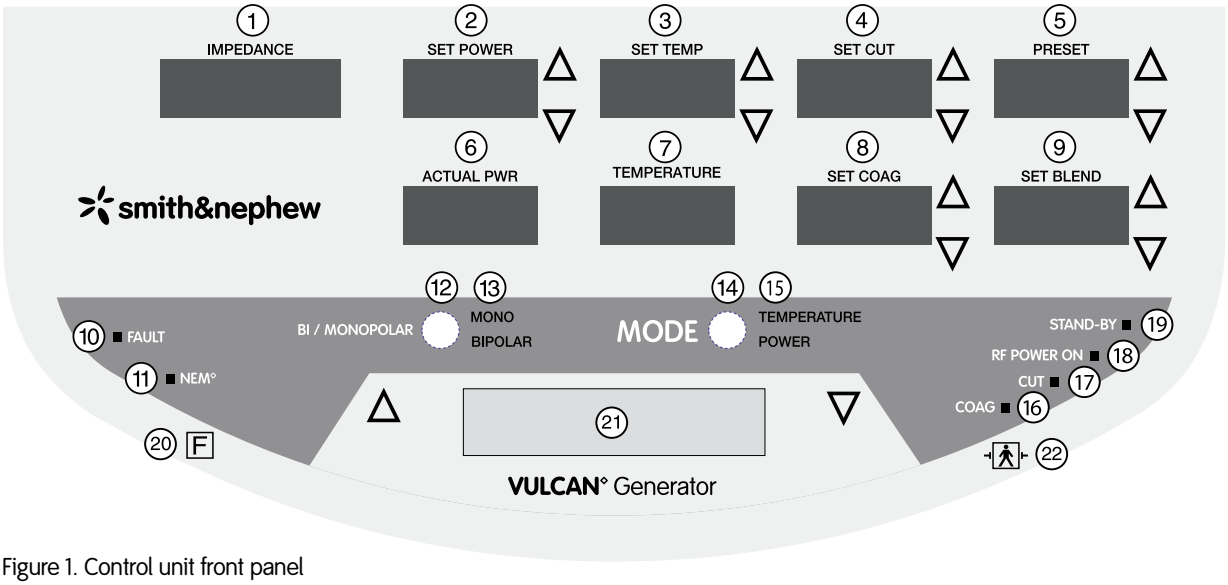


Figure 1. Control unit front panel

① **IMPEDANCE Display**

IMPEDANCE displays the impedance in ohms, measured at the tip of the probe. Active in both **Temperature Control** and **Power Control Modes**.

② **SET POWER Display with Up/Down Arrows**

SET POWER displays the maximum probe power output in watts, increased or decreased using the **SET POWER** up/down arrows. Active only in **Temperature Control Mode**.

③ **SET TEMP Display and Up/Down Arrows**

SET TEMP displays the target tissue temperature in degrees Celsius (° C), increased or decreased using the **SET TEMP** up/down arrows. Active only in **Temperature Control Mode**.

④ **SET CUT Display with Up/Down Arrows**

SET CUT displays the maximum probe power output in watts, increased or decreased using the **SET CUT** up/down arrows. Active only in **Power Control Mode** and the probe supports adjustment of **SET CUT**.

⑤ **PRESET Display with Up/Down Arrows**

PRESET displays the preset temperature and/or power combination chosen and is adjustable using the **PRESET** up/down arrows. Settings are displayed as 1, 2, 3, etc. Active in **Temperature Control** and **Power Control Modes** when the probe supports adjustment of **PRESET**.

⑥ **ACTUAL PWR Display**

ACTUAL PWR displays the actual power in watts delivered to the probe. Active only in **Temperature Control Mode**.

⑦ **TEMPERATURE Display**

TEMPERATURE displays the actual temperature in degrees Celsius (° C), measured at the tip of the probe. Active only in **Temperature Control Mode**.

⑧ **SET COAG Display with Up/Down Arrows**

SET COAG displays the maximum probe power output in watts, increased or decreased using the **SET COAG** up/down arrows. Active only in **Power Control Mode** and the probe supports adjustment of **SET COAG**.

⑨ **SET BLEND Display with Up/Down Arrows**

The **SET BLEND** mode is inactive for all probes.

⑩ **FAULT Indicator (Red Light)**

FAULT illuminates when a fault condition is detected.

⑪ **NEM Indicator (Green or Red Lights)**

NEM illuminates with a green light when the NEM circuit is correctly connected and with a red light when the NEM circuit is incorrectly connected. **NEM** will only illuminate when a monopolar probe is being used.

⑫ **BI / MONOPOLAR Button**

The **BI / MONOPOLAR** button selects the appropriate RF energy mode (monopolar or bipolar). The generator selects the appropriate mode automatically based on the probe type.

⑬ **BI / MONOPOLAR Indicator**

Either **MONO** (monopolar) or **BIPOLAR** is illuminated to identify the appropriate probe type.

⑭ **MODE Button**

The **MODE** button selects the appropriate RF energy delivery mode (**Temperature Control** or **Power Control**).

⑮ **MODE Indicator**

Either **TEMPERATURE** (**Temperature Control Mode**) or **POWER** (**Power Control Mode**) is illuminated to identify the appropriate generator mode.

⑯ **COAG Indicator (Blue Light)**

COAG illuminates when the generator control unit is delivering RF power and when the blue **COAG** (right) footswitch is pressed.

⑰ **CUT Indicator (Yellow Light)**

CUT illuminates when the generator control unit is delivering RF power and when the yellow **CUT** (left) footswitch is pressed.

⑱ **RF POWER ON Indicator (Green Light)**

RF POWER ON illuminates when the generator control unit is delivering RF power.

⑲ **STAND-BY Indicator (Green Light)**

STAND-BY illuminates when the generator control unit is in Stand-By Mode.

⑳ **Neutral (Return) Electrode Connector**

Accepts a dual–pin connector specifically designed for neutral electrode monitoring (NEM).

㉑ **Message Display**

Displays modes, probe type, alarms, warnings, or fault messages.

㉒ **Probe Connector**

Accepts 8-pin Smith & Nephew temperature-controlled, cutting, ablation, and hemostasis probes. The Smith & Nephew VULCAN• Extension Cable (REF 7209693) may be used with the generator control unit.

Rear Panel Layout

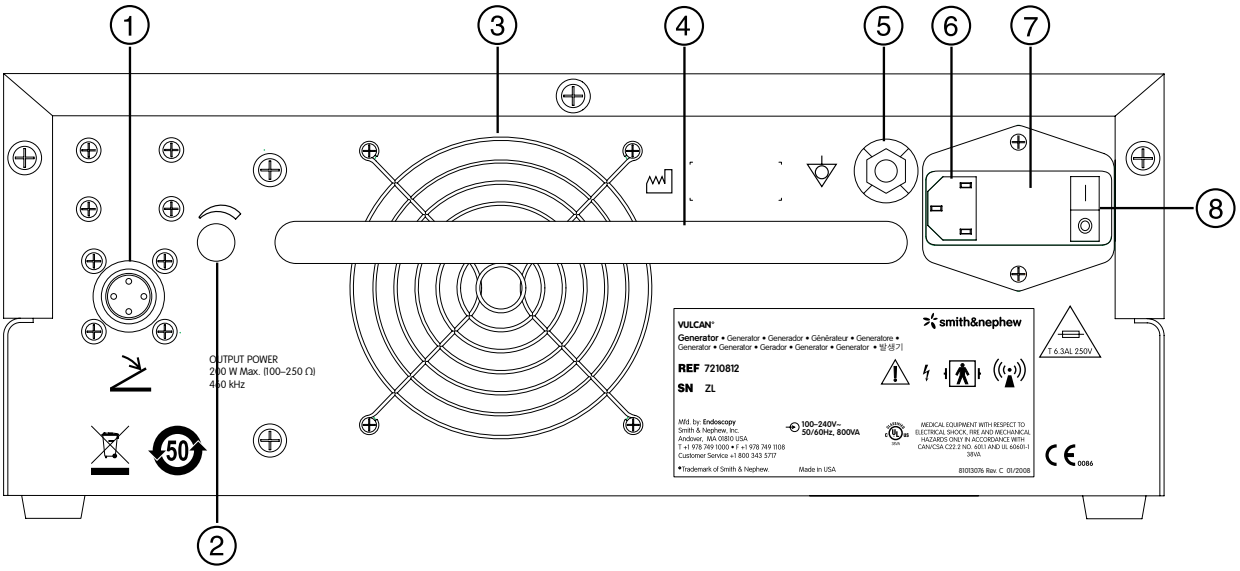


Figure 2. Control unit rear panel

① **Footswitch Connector**

Accommodates the generator footswitch cable supplied with the Smith & Nephew VULCAN• Generator.

② **Volume Control**

This knob adjusts the volume of the energy delivery tone.

③ **Fan Outlet**

④ **Carrying Handle**

⑤ **Equipotential Compensator Terminal**

This terminal can be used to bring other equipment to the same case potential as the generator control unit.

⑥ **Power Cord Connector**

The power cord connector is part of the power input module, and accommodates the hospital-grade power cord supplied with the Smith & Nephew VULCAN Generator.

⑦ **Fuse Access Door**

The fuse access door is part of the power input module. See the “Replacing Fuses” section for instructions on fuse replacement. To avoid hazards, use appropriate fuses as specified in the “Technical Specifications” section.

⑧ **On/Off Switch**

Rocker-type main power switch.

Preoperative Setup

WARNINGS:

- **DANGER: Risk of explosion if used in the presence of flammable anesthetics, skin preparation agents, or biointestinal gases.**
- **Hazardous electrical output. This equipment should be used only by qualified medical personnel trained in the use of electrosurgery devices.**
- **This device has been tested and verified to comply with the IEC 60601-2-2. This exceeds the requirements specified by FCC part 18 for ISM equipment. This device is intended for operation in a medical facility only. Usage in a residential environment will likely cause unacceptable RF interference for which the user is held responsible.**
- **The generator control unit must be powered from a properly grounded 120–240 VAC, single-phase supply. Excessive risk (leakage current) may result if this equipment is connected to other than the manufacturer's recommended power distribution system.**
- **Risk of burns or fire. Do not use near conductive materials such as metal bed parts, inner-spring mattresses, etc.**

1. Plug the power cord into the rear panel power cord connector and a grounded AC power source.

WARNING: Check that the electrical equipment is properly grounded (i.e., plugs contain a ground prong). The generator control unit must be plugged into a hospital-grade AC outlet.

2. Inspect the footswitch for any obvious defects. Connect the footswitch cable to the appropriate connector on the rear of the generator control unit.
3. Prepare the patient using standard technique for electrosurgical procedures. The patient's entire body, including extremities, must be insulated against contact with grounded metal parts, and sufficient layers of electrically insulating sheets should be placed underneath the patient. A waterproof cover should be placed over the insulating sheets, with absorbent sheets placed between the patient and the waterproof cover to absorb any moisture.

WARNING: The operating table should be grounded.

4. For monopolar procedures, affix the split grounding pad to the patient according to the instructions found in the pad packaging. Select a well-vascularized application site in close proximity to the surgical site. Avoid bony or hairy prominences. Shave, clean, and dry the application site as needed. Apply the pad firmly, assuring full adhesion and contact with the patient's skin. After the pad is properly applied to the patient, connect the pad to the NEM connector on the control unit front panel.

Note: It is important that the split grounding pad be connected to the generator control unit after the pad is properly placed on the patient. This allows the generator control unit to determine an accurate baseline split grounding pad contact quality measurement for a particular patient and will allow the system the greatest resolution in determining if a loss of split grounding pad contact occurs during the procedure.

WARNINGS:

- **Safe use of monopolar electrosurgery demands proper grounding of the patient and proper insulation between the patient and any metal surfaces. A split pad with a surface area of at least 20 square inches (130 cm^2) is required. Valleylab™ REM™ pads (REF: 7209687) meet this dimensional requirement and are recommended by Smith & Nephew for use with the VULCAN° Generator. Pads with a surface area of less than 20 square inches may have a lower dispersive effect. It is the responsibility of the user to qualify any alternate ground pad.**
- **Use of an inadequate ground pad or incorrect placement of the ground pad may result in a burn injury to the patient.**
- **Improper probe usage may result in patient burns at the return pad. To avoid this, follow the manufacturer's Instructions for Use.**

Operational Modes

Power Up

When the AC power to the generator control unit is turned on using the power switch on the rear panel, the generator performs a series of system self-tests to determine if it is performing properly. The self-tests include:

ROM checksum

RAM test

Temperature measurement calibration test

RF system test

Display segments and indicators test

If any of the system self-tests fail, the **FAULT** indicator on the front panel is illuminated and a continuous tone sounds. Contact Smith & Nephew if any system self-test fails.

WARNING: Failure of the radiofrequency surgical equipment could result in unintended increase of output power.

Stand-By Mode

Immediately after performing the self-test, the generator will default to **Stand-By Mode**. All of the displays on the front panel will be blanked, and the generator control unit will not be able to deliver RF power while it is in **Stand-By Mode**.

Fault Mode

If a fault is detected at any time during the generator control unit's operation, the **FAULT** indicator light will illuminate, an alarm will sound, an error code and text message will be displayed in the message display, and the generator will enter the **Fault Mode**. RF energy cannot be delivered and the control unit must be powered down then powered up again to exit from **Fault Mode**.

Power Delivery Modes

Temperature Control Mode

If the **MODE** button is pressed once while the generator is in **Stand-By Mode** or if a temperature controlled probe is connected to the generator, the generator will enter the **Temperature Control Mode**. In **Temperature Control Mode**, the Smith & Nephew VULCAN• Generator software automatically adjusts energy delivery to maintain the tissue temperature indicated in the **SET TEMP** display. Only monopolar temperature-controlled probes may be used in **Temperature Control Mode**.

All Smith & Nephew probes are equipped with a sensor that enables the generator control unit to detect the type of probe connected. When a probe is connected, the Smith & Nephew VULCAN Generator software will read the sensor and automatically adjust power output and temperature parameters to the preprogrammed settings for the probe type.

If a probe is not detected, the generator control unit will default to **PRESET** "1", and the **SET POWER** and **SET TEMP** displays will show the power and temperature values corresponding to this setting.

Power Control Mode

The generator enters **Power Control Mode** if the **MODE** button is pressed once while the unit is in **Temperature Control Mode**, or twice while in **Stand-By Mode**, or if a cutting or ablation probe is connected to the control unit.

The user may change the type and amount of power delivered by adjusting **SET CUT** (inactive for ELECTROBLADE• Resector) or **SET COAG** (inactive for GLIDER Articular Cartilage Probe).

All Smith & Nephew probes are equipped with a sensor that enables the generator control unit to detect the type of probe connected. When a probe is connected, the Smith & Nephew VULCAN Generator software will read the sensor and automatically adjust parameters to the preprogrammed settings for the probe type.

If a probe is not detected, the generator control unit will default to **PRESET** "10", and the **SET CUT** and **SET COAG** displays will show the **SET CUT** and **SET COAG** values corresponding to this setting.

Controls and Functions

SET POWER

SET POWER may be changed by pressing the up/down arrows located next to the **SET POWER** display. Power may be adjusted from 1–50 watts. Pressing the appropriate button repeatedly will adjust the power in increments of 1 watt; holding the button down will scroll through the power settings automatically.

SET TEMP

SET TEMP may be changed by pressing the up/down arrows located next to the **SET TEMP** display. Temperature may be set from 15–99° C. Pressing the appropriate button repeatedly will adjust the temperature in increments of 1° C; holding the button down will scroll through the temperature settings automatically.

SET CUT

SET CUT (inactive for ELECTROBLADE• Resector) may be adjusted by pressing the up/down arrows located next to the **SET CUT** display. Power may be adjusted from 1–200 watts or up to the preprogrammed limit for the probe type used. Pressing the appropriate button repeatedly will adjust the power in increments of 5 watts; holding the button down will scroll through the power settings automatically.

PRESET (Temperature Control Mode)

Commonly used temperature and power combinations are preprogrammed into the Smith & Nephew VULCAN• Generator software to allow the operator to quickly configure the generator control unit in **Temperature Control Mode**. Use the **PRESET** up/down arrows on the control unit front panel to select the desired setting. The selected setting will be displayed in the front panel **PRESET** display, and the corresponding temperature and power settings will be displayed in the **SET TEMP** and **SET POWER** displays.

PRESET (Power Control Mode)

Commonly used **SET CUT** and **SET COAG** power combinations are preprogrammed into the generator software to allow the operator to quickly configure the control unit in **Power Control Mode**. Use the **PRESET** up/down arrows on the control unit front panel to select the desired setting. The selected setting will be displayed in the **PRESET** display and the corresponding power settings will be displayed in the **SET CUT** and **SET COAG** displays. **PRESET** is inactive for ELECTROBLADE Resector and GLIDER Articular Cartilage Probes.

SET COAG

SET COAG (inactive for GLIDER Articular Cartilage Probes) may be adjusted by pressing the up/down arrows located next to the **SET COAG** display. Power may be adjusted from 1–200 watts or up to the preprogrammed limit for the probe type used. Pressing the appropriate button repeatedly will adjust the power in increments of 5 watts; holding the button down will scroll through the power settings automatically.

Auto Probe Recognition

The Smith & Nephew VULCAN• Generator software recognizes which type of Smith & Nephew probe is connected to the control unit by reading a sensor in the probe. When a probe is connected to the control unit, the software automatically switches to the appropriate control **MODE** and **PRESET** setting (if supported) for that specific probe.

The **SET TEMP**, **SET POWER**, **SET CUT**, and **SET COAG** settings may be changed from their preset values using the up/down arrows next to the respective displays (if supported by the probe).

The Smith & Nephew VULCAN Generator software also contains temperature and power limits for each probe type. The **SET TEMP**, **SET POWER**, **SET CUT**, and **SET COAG** settings cannot be set to values outside the range programmed in the software. This feature ensures that each probe type is used within its safe limits of operation.

Energy Delivery Tone

A tone sounds whenever RF energy is delivered. Volume is adjustable using the volume control knob on the control unit rear panel.

In **Power Control Mode** the tone is a steady sound while RF energy is delivered.

In **Temperature Control Mode** the tone sounds slowly while probe temperature is increasing. The tone sounds more rapidly as the set temperature is approached. The tone is rapid and steady when the set temperature is reached and while it is held. Any variation in tone speed signals the user that the probe temperature is not at the target temperature.

Fault Tone

The fault tone sounds briefly during generator control unit startup, and in the event of a warning or fault condition. The volume of the fault tone cannot be adjusted by the user.

Footswitch Connector

A dual, electrically-activated footswitch is provided to control RF energy delivery. The blue **COAG** (right) pedal is used with temperature-controlled probes and with **SET COAG** in **Power Control Mode**. The yellow **CUT** (left) pedal is used with cutting/ablation probes in **Power Control Mode**.

Temperature Control Mode

Yellow **CUT** pedal – inactive

Blue **COAG** pedal – enables coagulation output with temperature control

Power Control Mode

Yellow **CUT** pedal – enables cut output

Blue **COAG** pedal – enables coagulation output

Instructions for Use

1. Turn the control unit on using the on/off switch on the rear panel. The generator will perform a series of system self-tests to determine if it is performing properly. If any of these tests fail, the **FAULT** indicator will illuminate and a continuous tone will sound. Contact Smith & Nephew Customer Service if any system self-test fails. Inspect the front panel displays for any system indicator warnings or messages.

   After completing the self-tests, the generator will default to **Stand-By Mode**. All the displays on the front panel will be blank and the generator will not be able to deliver RF power.

2. Connect the selected Smith & Nephew probe to the probe connector on the control unit front panel. If the probe includes an integrated cable, insert the cable connector with the thumb groove up.

   For probes without an integrated cable, connect the probe to the extension cable. A “click” may be heard. Tug gently on the extension cable to ensure proper connection. Connect the other end of the probe cable into the probe connector.

   Note: ELECTROBLADE Resectors with a two-prong Valleylab plug end can be plugged into the ELECTROBLADE Adaptor for use with the VULCAN• Generator.

3. Verify that the selected probe’s name is presented on the message display. The generator software will recognize the probe type by reading a sensor in the probe and will automatically switch to the appropriate power output, **MODE**, and setting for that specific probe.

⚠ WARNING: Burns to the surgeon’s hands may be possible if a probe comes into contact with a metal instrument or surface.

CAUTION: *Check the probe and extension cable connections for the presence of liquid before use or whenever a probe is connected or disconnected during a procedure. Liquid may enter the connection during a procedure. ANY liquid can cause the connections to short, resulting in erroneous probe recognition or damage to the probe, cable, or generator control unit.*

CAUTION: *Check the generator control unit’s LCD message display to ensure that the proper probe identification and settings are displayed prior to beginning any procedure.*

4. Confirm that the NEM light is illuminated green. If illuminated red, check the split grounding pad to assure full adhesion and contact with the patient's skin.
5. If using a temperature-controlled probe, proceed to step 6. If using a power-controlled probe, skip steps 6–8 and proceed directly to step 9.
6. For temperature-controlled probes, check the temperature display to confirm expected values.

WARNING: Incorrect actual temperature readings may result in improper treatment. Verify that the TEMPERATURE display reads the expected value (room temperature or body temperature) prior to treatment. If the TEMPERATURE reading is not accurate, check the device and connectors for damage, moisture, or contamination. Clean or replace as needed.

CAUTION: *Use the lowest RF power settings necessary to achieve the desired tissue effect.*

7. To begin RF energy delivery, depress and hold the blue **COAG** footswitch for the type of power to be delivered, according to the probe's Instructions for Use. The green **RF POWER ON** and blue **COAG** indicator lights will illuminate.

WARNING: If desired tissue effect is not being achieved, do not increase power beyond the normal range without first inspecting the integrity of the probe and neutral (return) electrode.

8. During energy delivery, the generator sounds a fluctuating tone. The tone pulsates slowly while probe temperature is ramping up to the **SET TEMP**. The tone will sound more rapidly as the **SET TEMP** is approached. The tone is rapid and steady when the **SET TEMP** is reached and while it is held. Any variation in tone speed signals the user that probe temperature is not at the target temperature.
9. To begin RF energy delivery in the **Power Control Mode**, depress and hold the selected footswitch for the type of power to be delivered, according to the probe's Instructions for Use. Select the yellow **CUT** pedal for the cut output and the blue **COAG** pedal for the coagulation output. The green **RF POWER ON** and yellow **CUT** or blue **COAG** indicator lights will illuminate.

Note: During energy delivery in the **Power Control Mode**, a steady tone will sound while RF energy is being delivered. Different tones are generated for **CUT** and **COAG**.

WARNING: Do not exceed the RF duty cycle for the probe.

10. RF energy delivery may be discontinued at any time by releasing the footswitch. To resume RF energy delivery, press and hold the footswitch again.

WARNING: Do not withdraw the probe while energy delivery is activated; this may result in an unintended patient burn or ignition of flammable materials.

Cleaning and Sterilization

Generator Control Unit

The unit should be disconnected from the grounded AC outlet when being cleaned. The exterior surface of the control unit may be wiped down with any liquid disinfecting solution; non-flammable solution should be used. Care must be taken not to allow any liquid to pass into any electrical connections or the interior of the control unit. Let the surfaces dry thoroughly before plugging in the device. DO NOT steam sterilize the control unit. DO NOT immerse the generator control unit in glutaraldehyde or other liquid sterilant or disinfectant. DO NOT submerge control unit for any reason.

Smith & Nephew VULCAN° Extension Cable

The Smith & Nephew VULCAN Extension Cable (REF 7209693) is reusable and may be cleaned and sterilized as follows:

1. Rinse the cable with warm running tap water for a minimum of two minutes or until all visible debris is removed.
2. Place the cable in a bath containing Klenzyme™ (enzymatic detergent), prepared according to the manufacturer's instructions, for two minutes. Make sure that there is sufficient detergent to cover the cable.
3. Rinse the cable thoroughly under warm running tap water for one minute.
4. Prepare a solution of commercially available manual cleaner (i.e., Manu-klenz™) according to the manufacturer's instructions. Gently scrub the cable using a soft, non-metallic brush while the cable is immersed in the cleaning solution.

5. Rinse the cable thoroughly under warm running tap water for one minute.
6. Dry the devices with a soft, clean cloth.
7. Autoclave using the following parameters:
   - Dry time: No dry time needed.
   - Pre-vac: Four minutes steam exposure at 132–135° C.
   - Flash gravity: Ten minutes steam exposure at 131.5–133.5° C (target=132° C).

Note: Cables may be individually wrapped in surgical kraft paper and then placed in individual sterilization pouches prior to pre-vac sterilization.

Footswitch

The footswitch may be wiped down with any liquid disinfecting solution; non-flammable solution should be used.

CAUTION: *Do not immerse the footswitch cable.*

Probes

Smith & Nephew probes are disposable and are intended for single-use only. Do not attempt to clean or resterilize any Smith & Nephew probe.

Service and Maintenance

Service Philosophy

There are no user-serviceable components inside the generator control unit. Repairs and adjustments are to be performed only by Smith & Nephew authorized service centers.

If service becomes necessary, call your authorized Smith & Nephew Customer Service Representative prior to returning the device and request a Return Authorization (RA) number. Your representative can also explain the available Service Replacement and Repair Programs.

Service items should be carefully repackaged and returned post-paid to Smith & Nephew. Your Smith & Nephew Customer Service Representative can provide additional instructions.

Note: Product returned that is found to have been serviced by an unauthorized third party repair facility and/or sterilized with a sterilization method other than one approved by Smith & Nephew will incur additional costs, regardless of warranty status.

It is not necessary to include accessory items (i.e., power cords, footswitches, etc.) when returning a device for service.

Replacing Fuses

⚠ WARNING: To prevent electric shock, unplug the control unit from the electrical outlet before attempting to replace the fuses.

⚠ WARNING: To avoid fire hazard, use only fuses of the correct type, voltage rating, and current rating.

Note: Fuses that require frequent replacement may indicate an internal problem with the control unit. If fuses continue to blow, contact Smith & Nephew Customer Service for assistance.

To Inspect and/or Replace Fuses

1. Unplug the power cord from the power outlet and from the control unit.
2. Use a screwdriver to open the fuse compartment door on the AC receptacle (Figure 3) and slide out the two fuse carriers. Refer to the "Rear Panel Layout" section to locate the AC receptacle on the rear panel.
3. Replace fuses. See "Technical Specifications" section for replacement fuse types.
4. Reinsert the fuse carriers using the arrows on the inside of the fuse compartment door as a guide.
5. Snap the fuse compartment door closed.

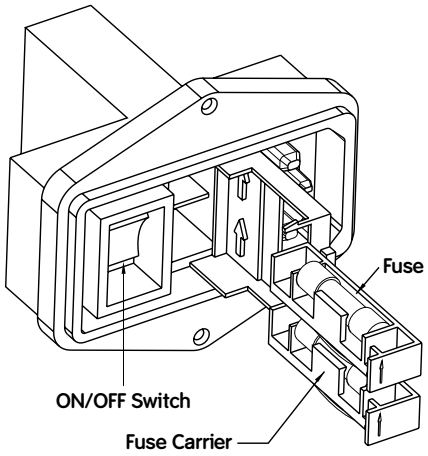


Figure 3. AC receptacle with fuses

Software Upgrades

For information regarding software upgrades, please contact your local authorized Smith & Nephew representative.

Replacing/Returning Worn or Defective Equipment or Parts

Contact Smith & Nephew Customer Service to order replacement footswitches, extension cables, or any other accessory, and for instructions on disinfection and return of worn-out or defective equipment or parts.

Other than fuses, the Smith & Nephew VULCAN• Generator has no customer-serviceable parts. For service, please contact your representative or Smith & Nephew Customer Service.

Preventative Maintenance

The following inspections should be performed on an annual basis to ensure safe operation of the Smith & Nephew VULCAN Generator.

Inspection of Cables

Inspect the power cable and replace if signs of wear or abrasion are visible.

Inspection of Connectors

Inspect all connectors on the control unit for signs of wear or damage. Look specifically for bent or damaged pins, loose fittings, etc. Contact Smith & Nephew Customer Service for assistance if any damage is detected.

Calibration of Temperature Measurement Circuit

There is no method for the user to alter the calibration of the temperature measurement hardware in the field. However, Smith & Nephew recommends that this calibration be checked on an annual basis. If it is found to be out of specification, the device should be returned to Smith & Nephew for repair.

The generator performs a self-test during power-up to verify power calibration. There is an internal, 100 ohm resistor which is measured and compared to its specified value. The generator goes into a **Fault Mode** if the calibration is out of specification. In addition, the thermocouple amplifying circuits are checked for calibration. However, there is no check on the "absolute" temperature measured by a temperature probe; therefore, this calibration must be manually checked.

Equipment

- Thermometer
- TAC•-S Probe with connecting cable
- Beaker

Procedure

1. Fill the beaker with cool water (10–30° C).
2. Use the thermometer to measure and record the temperature of the cool water.
3. Turn on the control unit and connect the cable of the test TAC-S Probe. Verify that the control unit goes into the **Temperature Control Mode**. The **TEMPERATURE** should display room temperature.
4. Immerse the tip of the TAC-S Probe in the water and record the actual temperature.
5. Repeat steps 1–4 using hot water (50–90° C).

The **TEMPERATURE** reading with the TAC-S Probe should be +/- 3° C of the thermometer reading in both cases.

If a greater difference is observed, contact Smith & Nephew for assistance.

Troubleshooting

Generator Control Unit

The generator control unit includes a message display that provides a text description of any alarm or fault messages. If the system is not operating as expected, check the message display.

WARNING: To prevent electric shock, do not remove the control unit cover. There are no user-serviceable components inside. Dismantling the equipment will void the warranty. Refer servicing to qualified Smith & Nephew personnel.

Alarm and Fault Messages

The generator detects two types of error conditions: alarms and faults.

An alarm is generated to inform the user that the output of the device is being disabled to prevent injury to the patient or damage to the device. Alarms are automatically cleared once the alarm condition returns to its acceptable value.

A fault is a more serious error condition and typically occurs as a result of a hardware failure, such as a stuck footswitch or a conversion circuit that is out of calibration. The **FAULT** indicator light will be illuminated, and requires that the control unit be reset by cycling power. Refer to the “Troubleshooting” section for those faults that can be corrected by the user. If a fault other than those listed occurs, contact Smith & Nephew for assistance.

Alarm and Fault Messages (continued)

Type	Message	Condition	Possible Remedy
Alarm	**OPEN TC– RF disabled in Temp Control mode** (**Note:** "OPEN TC" refers to an open thermocouple circuit.)	RF output is not allowed in the **Temperature Control Mode** unless a valid temperature measurement is returned from the probe's temperature sensor.	• Check probe connection to generator control unit. • Replace probe.
Alarm	**Cannot use CUT pedal in Temp Control mode**	RF output is disabled in the **Temperature Control Mode** if the yellow **CUT** footswitch is pressed.	Use **COAG** pedal.
Alarm	**RF Disabled – Check Return Electrode**	RF output is disabled in any monopolar mode if the impedance between the electrodes on the split grounding pad is greater than the calculated threshold.	Check that the return electrode is properly applied to the patient and that the cable is properly connected to the generator control unit.
Alarm	**LOW LOAD IMPEDANCE– Output power reduced**	RF output is reduced to below 5 watts whenever the measured load impedance is less than 40 ohms (or 20 ohms depending on the probe).	Keep active electrode away from metallic surfaces during use.
Alarm	**NEM CIRCUIT SHORTED– Use split-pad return**	If the impedance calculated during NEM initialization is less than 5 ohms, the unit indicates a NEM contact failure.	• Check that split grounding pad is being used. • Check that the split grounding pad is properly applied to the patient and that the pad is properly connected to the front of the control unit. • To test for proper operation of the NEM circuitry, unplug the neutral electrode and connect a 100 ohm, non-inductive resistor across the two pins of the neutral electrode connector. The impedance should be sufficiently high to clear the alarm. If the alarm persists, contact Smith & Nephew.*

**Call Smith & Nephew Technical Support at 1-800-343-5717 in the U.S., or your local Smith & Nephew representative.*

Alarm and Fault Messages (continued)

Type	Message	Condition	Possible Remedy
Alarm	**POWER FACTOR LOW – Output power reduced**	RF output is reduced to below 5 watts whenever the calculated power factor is less than 0.2.	Keep active electrode away from metallic surfaces during use.
Alarm	**Can't use COAG pedal with this probe**	The use of the **COAG** pedal is not supported with the connected probe.	Use the **CUT** pedal.
Alarm	**RF Disabled – No Probe Detected**	A footswitch was pressed when no probe was connected.	Connect a probe prior to pressing a footswitch.
Alarm	**Cannot use Temp Cont Probe in Power Mode**	A thermocouple was detected on a probe.	Use the **Temperature Control Mode**.
Alarm	**Cannot use CUT pedal with Electroblade**	The **CUT** pedal was used with the Smith & Nephew DYONICS® Electroblade® Resector	Use the **COAG** pedal.
Fault	**CJC Out of Range**	The cold-junction compensator (CJC) portion of the thermocouple circuit has detected a room temperature outside the expected range of 10–35° C. This may occur if the control unit was exposed to extreme temperatures.	Let generator reach room temperature.
Fault	**Footswitch Stuck On**	One or both footswitches was activated during start-up.	• Check each footswitch to make sure a cord or other object is not interfering with the footswitch connection. • Reset the control unit by turning it off and then back on again.

Alarm and Fault Messages (continued)

Type	Message	Condition	Possible Remedy
Fault	**Output Load Shorted**	The load impedance fell below 40 ohms for longer than is permissible (20 ohms depending on probe).	• Check that probe is not shorted to the surgical cannula or arthroscope. • If no contact to the cannula/ arthroscope is seen, the probe or probe cable may be defective. Remove the probe from the surgical site and reset the control unit (turn off, then on). With the probe in free air, activate the footswitch and note the **IMPEDANCE** reading displayed. If **IMPEDANCE** is less than 500 ohms, either the probe or probe cable may be defective. • Replace the probe cable and repeat impedance check. If **IMPEDANCE** is greater than 500 ohms, the cable was defective. If **IMPEDANCE** is still less than 500 ohms, the probe may be defective. Contact Smith & Nephew.* • Replace probe and repeat impedance check. If **IMPEDANCE** is greater than 500 ohms, the probe was defective. If **IMPEDANCE** is less than 500 ohms, the control unit may need service. Contact Smith & Nephew.*
Fault	**RF Board Overtemp**	The temperature of the heat sink on the RF power control board has exceeded its specified threshold. Aggressive use of the system, either for an excessive period of time or at excessive power levels, may cause this fault.	Reduce output power or increase idle time between periods of RF power delivery.

**Call Smith & Nephew Technical Support at 1-800-343-5717 in the U.S., or your local Smith & Nephew representative.*

Observed Problems

If no alarm or fault messages are displayed and the generator is not performing as expected, check the following list of conditions for possible remedies. Contact Smith & Nephew if the suggested remedies do not correct the condition.

Condition	Possible Remedy

Insufficient tissue response/tissue not reaching desired temperature.	Possible cause: Temperature never reaches **SET TEMP**.
	• Ensure probe tip is in direct visual contact with the target tissue. Probe should be moved slowly across the tissue.
	• Ensure footswitch is continuously depressed during energy delivery.
	• **ACTUAL PWR** should reach or approach **SET POWER**.
	• Increase **SET TEMP** by 5° C and observe tissue response.
	
	Check **IMPEDANCE** reading.
	1. If **IMPEDANCE** is less than 40 ohms (20 ohms depending on probe), software will reduce power to 5 watts:
	  • Ensure that probe tip is NOT in contact with any metal cannula, conductor or instrument.
	  • Replace connector cable.
	  • Turn control unit off and then on again. If problem is not resolved, replace probe.
	2. If **IMPEDANCE** is greater than 200 ohms:
	  • Ensure **SET POWER** is set to desired wattage.
	  • Inspect the neutral electrode for proper connection and patient placement (see "Preoperative Setup" section).
	
	Check the cable for proper connection.
	• Disconnect and reconnect the extension cable at the control unit and at the probe. See "Preoperative Setup" section for detailed instructions.
	• With the probe in contact with tissue and the generator delivering energy, flex the cable near the generator and probe end connections. If **IMPEDANCE** value dramatically changes (+/- 500 ohms), replace cable.
	
	If an arthroscopic fluid pump is being used:
	• Reduce pump pressure and outflow as much as possible.
	• Close, seal or cap leaking cannulas to minimize flow through joint.
	• Switch to gravity flow.
	
	Inspect the probe shaft insulation:
	• Clean coagulum off probe tip.
	• If shaft insulation is not intact, probe may be losing energy through the saline. Replace probe.
	
	If the probe was bent or aggressively handled, replace the probe. Insulation damage or thermocouple sensor in probe tip may be damaged.
	
	Other considerations:
	• Older patients (age greater than 40 years) may exhibit a slower and less dramatic tissue response.
	• If patient has a history of prior surgery, scar tissue may not respond to treatment.
	• Patient size may be a factor. Thicker or larger treatment areas may take longer to react.

Observed Problems (continued)

Condition	Possible Remedy
"OP" in the Temperature display.	1. Ensure probe is connected properly (see "Preoperative Setup" section for connection details). 2. With probe attached, flex the cable near the generator control unit and probe end connections. If "OP" changes to a temperature reading, replace the cable. 3. If "OP" is still displayed after flexing the cable, replace the probe.
No indicators or read-outs are displayed when the control unit is turned on.	1. Be sure the control unit is plugged into a working electrical outlet and the power switch at the rear of the unit is turned on. 2. Unplug the control unit and inspect the integrity of the fuses in the rear panel. Fuses should only be replaced with those of the same type and rating according to the label on the rear of the unit or the "Technical Specifications" section.
RF power does not turn on when footswitch is pressed.	1. Verify that the footswitch is properly connected to the back of the control unit. 2. Verify that only one of the two footswitches is activated. 3. In **Temperature Control Mode**, only the blue **COAG** (right) footswitch is active. Verify that the blue **COAG** footswitch is the one in use. 4. In **Temperature Control Mode**, verify that a temperature-controlled probe is in use. 5. Compare **SET TEMP** to **TEMPERATURE**. If **TEMPERATURE** is not close to **SET TEMP**, the thermocouple in the probe may be defective. RF delivery is disabled in this condition.
FAULT indicator light stays on and the generator emits a continuous tone.	Turn control unit off and back on. If light stays on, contact Smith & Nephew.*
RF interferes with other equipment.	1. Ensure the probe or neutral electrode cables do not cross the cables from the affected equipment. Changing the settings on the affected equipment may alleviate interference. 2. Plug the affected equipment into a separate power outlet.
Delivered power displayed on the **ACTUAL PWR** readout will not go above 5 watts.	1. If **IMPEDANCE** reading is 40 ohms or lower (20 ohms depending on probe), ensure that the probe tip is NOT in contact with any metal conductor or instrument. 2. Turn the control unit off and back on. If issue does not resolve itself, the control unit may need repair. Contact Smith & Nephew.*
Temperature reads "OP" and a temperature-controlled probe is being used.	1. Ensure that the control unit is in **Temperature Control Mode**. 2. Ensure that the probe extension cable is properly plugged into the jack and that the probe is properly plugged into the other end of the cable (the white markers should line-up and there should be a positive click). 3. If steps 1–2 do not solve the problem, replace the extension cable. 4. If step 3 does not solve the problem, replace the probe.

**Call Smith & Nephew Technical Support at 1-800-343-5717 in the U.S., or your local Smith & Nephew representative.*

Observed Problems (continued)

Condition	Possible Remedy
Temperature consistently overshoots **SET TEMP**.	1. Decrease **SET POWER** 1–5 watts. 2. Maintain constant tissue contact and steady probe movement.
NEM light is red.	1. The split grounding pad is not properly attached. 2. Make sure that a split grounding pad is properly placed and is connected to the control unit. 3. Replace the split grounding pad, being careful to check for proper application to the patient.
Auto Probe Recognition does not work or no readings are displayed on the control unit.	1. Check probe/cable connection. 2. Change the cable if necessary. 3. Turn power off, then on again. 4. Change the probe if necessary.
Cannot set desired power or temperature level.	The control unit includes circuitry to detect the type of surgical probe that is connected, and to limit the maximum power/temperature settings based on the intended use and ratings of the probe. Check the message display to ensure that the control unit has properly detected the type of probe that is connected. Indication of an incorrect probe may be the result of either a defective cable or probe.

Technical Specifications

Input Power

100–240 V~, 50/60 Hz, single phase

Rated Power Input

800 VA

Output Power

Temperature Control Mode: 50 watts

(+/- 20%) into 250 ohms

Power Control Mode: 200 watts (+/- 20%) into 250 ohms

Maximum Open Circuit Voltage (peak to peak)

Temperature Control Mode: 392 V

Power Control Mode: 1070 V

Operating Frequency

460 kHz (+/- 5kHz)

Waveform

Quasi-sine wave

Fuses

Dual fuses: T6.3AL250V

RF Duty Cycle

Temperature Control Mode:
20 seconds on/10 seconds off

Power Control Mode:
5 seconds on/5 seconds off

Set Temperature Range

15–99° C (in Temperature Control Mode)

Set Power Range

Temperature Control Mode: 1–50 watts

Power Control Mode: 1–200 watts

Operational Modes

Power Up, Stand-By, Ready, Fault

Power Delivery Modes

Temperature Control, Power Control

Dimensions (Height x Width x Depth)

5.5" x 13.8" x 17.9"

(14.0 cm x 35 cm x 45.5 cm)

Weight

25 lbs. (11.4 kg)

Protection

Class I, Type BF Applied Part—defibrillator proof, IXP0, continuous operation. This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

Environmental Conditions

	Transport and/or Storage	Use
Temperature	-20°–60° C (-4°– 40° F)	10°–35° C (50°–95° F)
Humidity	20–90% (no condensation allowed)	30–75%
Atmospheric Pressure	500–1060 hPa	500–1060 hPa

Ordering Information

Each Smith & Nephew VULCAN• Generator system (country specific) includes a VULCAN Generator, country-specific power cord, footswitch, and country-specific Operations/Service Manual. The International System (REF 7210869) includes a European Continental power cord.

REF	Description
7210868	Smith & Nephew VULCAN Generator System, U.S.
72201480	Smith & Nephew VULCAN Generator System, German
72201481	Smith & Nephew VULCAN Generator System, Spanish
72201482	Smith & Nephew VULCAN Generator System, French
7210872	Smith & Nephew VULCAN Generator System, Italian
72201484	Smith & Nephew VULCAN Generator System, Swedish
72201485	Smith & Nephew VULCAN Generator System, Dutch
72201486	Smith & Nephew VULCAN Generator System, Portuguese
72201487	Smith & Nephew VULCAN Generator System, Danish
72201488	Smith & Nephew VULCAN Generator System, Norwegian
72201489	Smith & Nephew VULCAN Generator System, Korean
7210870	Smith & Nephew VULCAN Generator System, UK
7210869	Smith & Nephew VULCAN Generator System, International
7210812	Smith & Nephew VULCAN Generator
7209693	Smith & Nephew VULCAN Extension Cable
7209692	Smith & Nephew VULCAN Footswitch
7209687	Split Grounding Pad
7209597	Probe Tip Bender

CAUTION: *Inspect all components, including extension cables and power cord, regularly for wear. Pay particular attention to extension cable insulation. Replace if evidence of deterioration is noted.*

CAUTION: *The Smith & Nephew VULCAN• Generator is designed specifically for use only with Smith & Nephew arthroscopic radiofrequency probes. Do not use other devices with the generator control unit.*

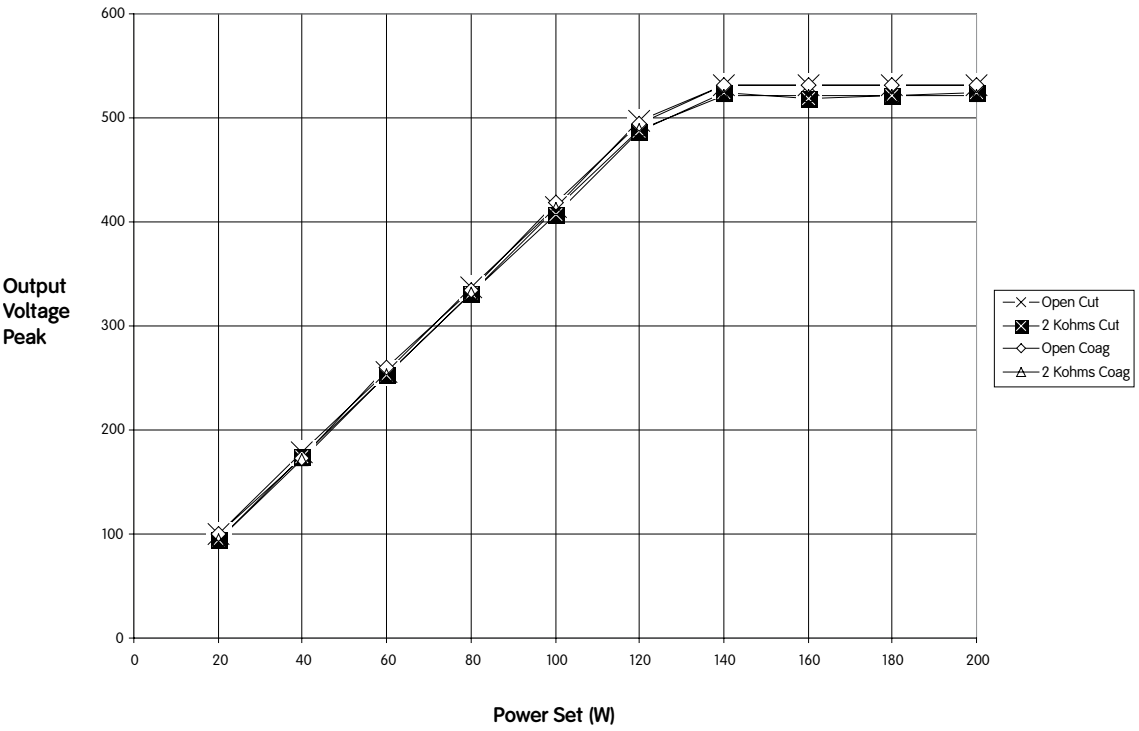
Note: Smith & Nephew VULCAN Extension Cables may only be reused in accordance with the instructions in the "Cleaning and Sterilization" section.

Note: Contact Smith & Nephew or visit the Smith & Nephew web site for the most current list of available arthroscopic RF products.

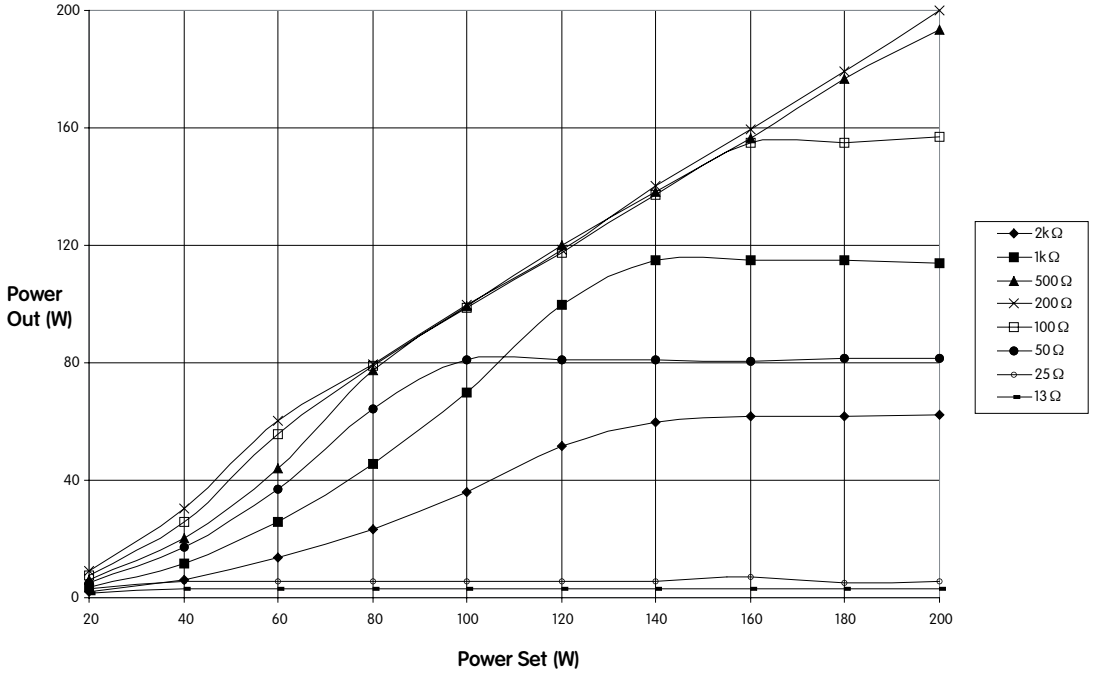
IMPORTANT: Accessories connected to the generator control unit must be capable of withstanding the highest RF peak voltage output. Refer to "Output Charts" section for suitable ratings prior to connection and/or RF application.

Output Charts

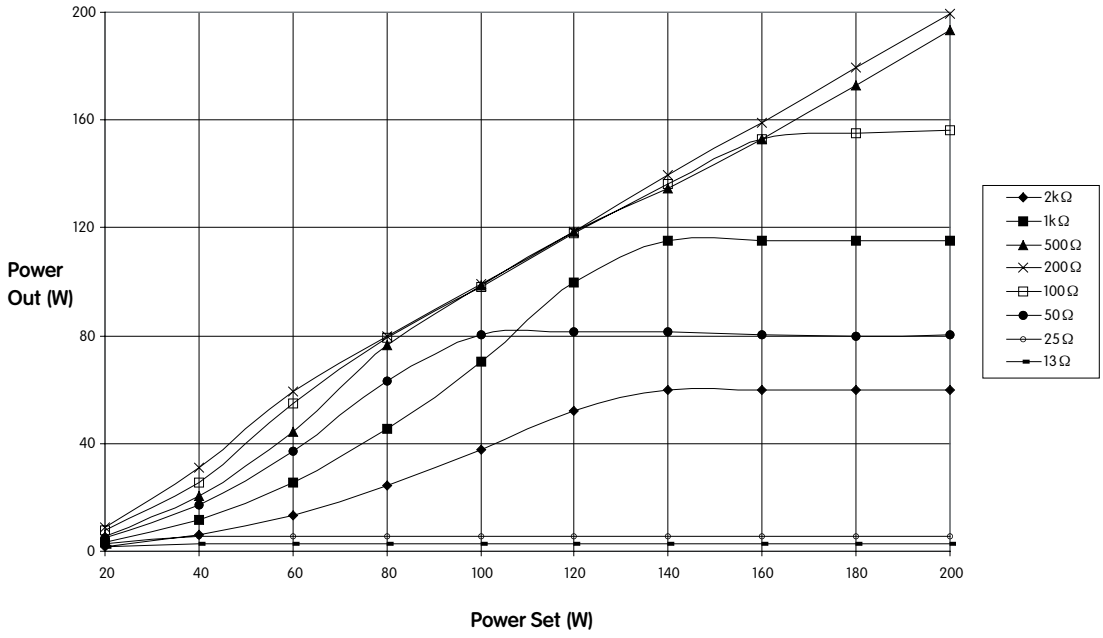
Output Voltage vs. Output Control



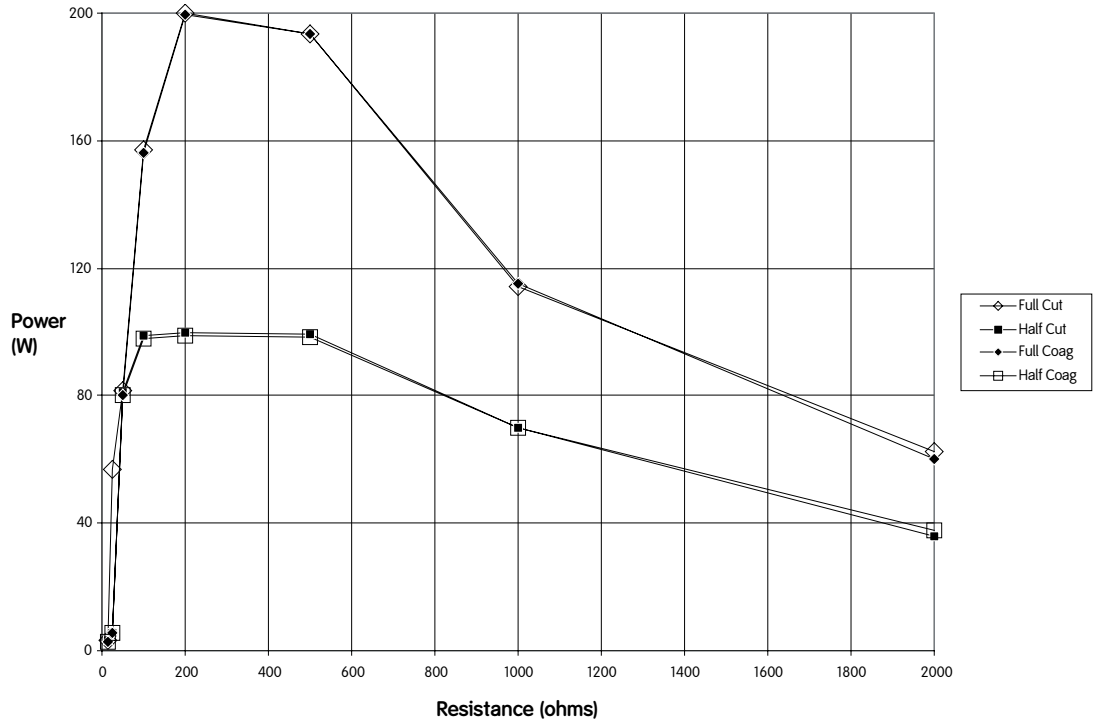
Power Output vs. Output Control Cut Mode



Power Output vs. Output Control
Coag Mode



Power Output vs. Load Resistance



Guidance and Manufacturer's Declaration – Electromagnetic Emissions*		
The Smith & Nephew VULCAN• Generator is intended for use in the electromagnetic environment specified below. The customer or user of the VULCAN Generator should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 2	The VULCAN Generator must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The VULCAN Generator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

**Applies only to Smith & Nephew VULCAN Generator REF 7210812. Does not apply to Smith & Nephew VULCAN Generator REF 7209673.*

Guidance and Manufacturer's Declaration – Guidance for Separation Distances*			
Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Smith & Nephew VULCAN Generator			
The VULCAN Generator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the VULCAN Generator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VULCAN Generator as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter W	**Separation Distance According to Frequency of Transmitter m**		
	150 KHz to 80 MHz $d = 1.2 \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2 \sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

**Applies only to Smith & Nephew VULCAN Generator REF 7210812. Does not apply to Smith & Nephew VULCAN Generator REF 7209673.*

Guidance and Manufacturer's Declaration – Electromagnetic Immunity*			
The Smith & Nephew VULCAN• Generator is intended for use in the electromagnetic environment specified below. The customer or user of the VULCAN Generator should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	+/- 1 kV differential mode +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the VULCAN Generator requires continued operation during power mains interruptions, it is recommended that that VULCAN Generator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristc of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

**Applies only to Smith & Nephew VULCAN Generator REF 7210812. Does not apply to Smith & Nephew VULCAN Generator REF 7209673.*

Guidance and Manufacturer's Declaration – Electromagnetic Immunity*			
The Smith & Nephew VULCAN• Generator is intended for use in the electromagnetic environment specified below. The customer or user of the VULCAN Generator should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the VULCAN Generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	3 Vrms	$d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/M 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio, (cellular/cordless) telephones, land mobile radios, amateur radios, AM and FM radio broadcasts, and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the VULCAN Generator is used exceeds the applicable RF compliance level above, the VULCAN Generator should be observed to verify normal operation. If abnomal performance is observed, additional measures may be necessary, such as reorienting or relocating the VULCAN Generator. [b] Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.			

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Warranty

Smith & Nephew products are guaranteed to be free from defects in material and workmanship for the warranty period for a particular product, beginning from date of invoice. Refer to the current Smith & Nephew Product Catalog or contact Smith & Nephew Customer Service for specific warranty information.

This limited warranty is restricted to repair or replacement by Smith & Nephew, at its option, of any product found to be defective during the warranty period. Damage inflicted to a product by the user that causes it to be unsuitable for refurbishment may result in additional charges, regardless of warranty status. All warranties apply to the original buyer only. In no event shall Smith & Nephew be liable for any anticipated profits, consequential damages, or loss of time incurred by the buyer with the purchase or use of any product.

NO OTHER WARRANTY, EXPRESSED OR IMPLIED, IS GIVEN.

Service Replacement Units Warranty

Smith & Nephew service replacement units are warranted to be free from defects in material and workmanship for the warranty period for a particular product, beginning from date of invoice. Refer to the current Smith & Nephew Product Catalog or contact Smith & Nephew Customer Service for specific warranty information.

Service Replacement Program

Smith & Nephew offers a 24-hour Service Replacement Program for its products to minimize downtime in your operating room. Our goal is to ship you a service replacement unit within 24 hours** of your call (during normal business hours). For a Return Authorization (RA) number or for additional information on this program, call Customer Service at +1-800-343-5717 in the U.S., or contact your authorized representative.

***24-hour shipment is not offered in all countries.*

Repair Service Program

For devices no longer under warranty, repairs can be made by Smith & Nephew or by an authorized agent. Non-warranty repairs will be made at the list price of replacement parts, plus labor. If requested, we will provide an estimate of repair cost and time required for the repair before any work is done. Repair items should be carefully disinfected, repackaged, marked with the Return Authorization (RA) number, and returned postpaid to the appropriate Smith & Nephew Service Center. Smith & Nephew Customer Service or your local authorized representative can provide shipping information.

EC REP

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